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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,907	11/02/2001	Subramaniam Srikumaran	UNL 3060.2	7717
321 7590 10/21/2003 SENNIGER POWERS LEAVITT AND ROEDEL ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			EXAMINER LI, BAO Q	
			ART UNIT 1648	PAPER NUMBER 9
DATE MAILED: 10/21/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/003,907

Applicant(s)

SRIKUMARAN, SUBRAMANIAM

Examiner

Bao Qun Li

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 22-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 1-39 are pending.

#### ***Response to Amendment***

This is a response to the amendment, paper No. 8, filed 08/11/03. Claim is has been amended. Claims 1-21 are considered before the examiner.

Applicants are reminded to cancel the claims 22-39 drawn to the non-elected groups.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

#### ***Double Patenting***

Applicants fails to response to Office Action regarding the Double patenting issue. The rejection is still maintained on the record.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-21 is still rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for eliciting an immune response by using a immune complex comprising a heat shock protein fused or conjugated with a viral antigen protein or viral antigen peptide in vitro or expressed by a cell line, does not reasonably provide enablement for using an immune complex to induce an immune response, wherein the complex comprising at least one heterologous or homologous heat shock protein and a viral epitope generated in vitro and in vivo. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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3. Applicants transverse the rejection and argue that the specification provides a person skill in the art with a guidance in respect to the use of an vector encoding a bovine HSV antigen epitope expressed in cells and the isolation of epitope-HSV complex from the vector-infected host cell line. Then, the purified HSP/antigen can be further administered into an animal to elicit an immune response.

4. Applicants' argument has been fully considered; however, it is not found persuasive because expression an immune epitope by a vector in a host cell line is still considered as an in vitro experimentation and is not equivalent to the isolation an HSP/antigen epitope complex from a host in vivo because the claim 14 read on the purified epitope/heat shock protein complex is formed in vivo.

5. Moreover, the specification does not teach which 5 to 25 amino acids of an epitope for each pathogenic virus as listed in claims 5 to 8 are.

6. Therefore, it is still concluded that an undue experimentation is still required for a person skill in the art to practice the full scope of the invention. The rejection is maintained.

#### **New Ground Rejection:**

#### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 2-21 are still rejected under 35 U.S.C. 112, first paragraph on the same ground as stated in the previous Office Action, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

9. Applicants argue that the supermotif and allele specific peptide motif of BoLa-A0 have been described in the specification. The literatures of prior art , such as Hedge et al. and

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Sawhney et al. disclosed the gene encoding a BoLA-A11 antigen et al. Therefore, a skilled artisan would discern that the applicants were in possession of a supermotif or an allele specific peptide motif of BoLA-A11 as employed in the method of claims 2-4 and 21.

10. Furthermore, Applicants argue that the claimed invention is a method but not directed to a nucleic acid sequence, wherein the method does not dependent on any particular epitope. In face, the identity of the epitope need not even be known to practice the claimed method.

11. Applicants' argument has bee fully considered; however, it is not found persuasive because the Case law of Eli Lilly is to indicate that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds but it makes no reference to the compound in question, the "written description" requirement has not been met even though the description may be enabling. In the instant case, the claimed invention is directed to use certain supermotif or allele specific motif with a particular size of amino acids, such as claims 5-8, the specification has made no reference to the structure for all of these HSP/epitope complexes with an allele specific peptide motif or supermotif of BoLA-A11 or in questions.

### Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Bao Qun Li

October 06, 2003